

REMARKS

Independent Claims 1-11 and 34-53 were previously canceled without prejudice to the filing of continuation and divisional applications. Claims 12, 55 and 56 are amended to delete language related to glass transition temperature and to point out that melt blending results in the drug reservoir. Support for the amendment can be found in the application, for example, in the original claims. Claim 12 and 55 are amended to include a more closed scope by the phrase "consisting essentially of". Support for the amendment can be found in the application, for example, the original claims and the examples. Claims 13, 14, 15, and 54 are amended to comport with the changes in the claim from which they depend, i.e., claim 12. Support for the amendment can be found in the application, for example, in the original claims. New claim 57 has been added to address the inclusion of specific drugs. Support for the claim can be found in the application, for example, in the original claims. No new matter is added in the amendments and new claims. Claims 12-33 and 54-57 are pending.

Interview Summary

Applicants note with appreciation the courtesy extended to Applicants' attorney, Philip Yip, in the telephone interview of January 26, 2006. During the interview, prior art references were discussed. Applicants' Attorney also proposed using "consisting essentially of" instead of "comprising" relating to the polymer in some of the claims.

35 USC §112 Rejection

The Examiner rejected claim 12 under §112 first paragraph as failing to comply with the written description requirement in that nowhere in the specification Applicant had disclosed glass transition temperature property of polyurethane polymer. The rejection is respectfully traversed.

Applicants respectfully point out that in the middle paragraph of page 4 of the specification Applicants described transition temperature for components of polyurethane. Further, from the description of melt-blending at below about 150 °C, anybody skilled in the art will know Applicants refer to transition temperatures of the polyurethane enables melt-blending of the polyurethane as described in the present invention. Nevertheless, to speed the prosecution

of the application, Applicants have deleted the language on glass transition temperature. Withdrawal of the rejection is requested.

35 USC §103 Rejection

The Examiner rejected claims 12-20, 22, 33, 54-56 under 35 USC 103 as being unpatentable over Rc 32991 ('991, Szycher) in view of US 6010715 ('715, Wick). Applicants respectfully traverse the rejection.

'991 discloses a drug containing material of elastomeric material that has been **UV-CURED** (see '991, column 5, and the examples). This material is said to be "**fully cured, solvent-resistant**" (see, e.g., '991, column 6, line 31, 61). Curing changes the thermal and mechanical property of a material, due to cross-link in the curing reaction. For example, everybody knows the thermal properties of rubber material before and after vulcanizing are vastly different. Such significant changes are evident even from '991 itself. Before UV curing, the polyurethane Tecoflex EG-60D is dissolved in a solvent, but after UV curing, the resulting film is solvent-resistant, as shown in the above cites. Similarly, a person skilled in the art will know there are significant changes in thermal property in UV curing. A person skilled in the art will know that such a material is not melt blendable, let alone melt blendable at below about 150 °C. The Examiner asserted that Tecoflex is used in '991, but the additional inclusion of UV curable oligomer and the process of UV-curing in '991 render the material not melt-blendable regardless of what property the polyurethane had before UV curing. Any person skilled in art will know that such UV-cured polymers cannot be melt-blended. UV curing is an irreversible chemical reaction. Once cured, the material cannot be uncured. Thus, the polyurethane in the UV-cured material cannot be melt-blended anymore. Neither can the UV-cured film with the cured polyurethane and oligomer.

Furthermore, the polyurethane Tecoflex EG-60D cited in '991 does not have the same product number as described in the present invention. After UV-curing, the thermal property of the '991 material could be even farther away from that of the polyurethane polymer of the present invention.

Thus, nobody skilled in the art will be lead by '991 to think that polyurethane can be melt-blended with a drug **to result in** the drug reservoir, let alone melt-blended at below about 150 °C.

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Further, it is noted that in '991, the UV-cured film is made *in a solvent* to form the drug containing material. This further teaches away from the present invention, since in the presently claimed invention, we specifically stated that the melt-blending can be done *without solvent*.

Further, '991 is about a wound dressing and entirely unrelated to transdermal drug delivery. Obviously a wound dressing is placed on a wound through which drug can pass. This is entirely different from a transdermal delivery system. In transdermal drug delivery, the drug has to pass through the reservoir and through the body surface (such as skin). What works well for an open wound may fail miserably in transdermal delivery. Thus, the use a material for a wound dressing gives no suggestion or expectation of success for use of such in a transdermal delivery system. Thus, '991 is entirely irrelevant to the present invention.

It is further noted that '715 Wick does not disclose a device with polyurethane having a process temperature of less than 150 °C. For example, at the bottom of column 4 of Wick, the melt-blending temperature is between about 170 °C and 200 °C, which is significantly higher than what we claims. Such high temperatures are detrimental to many drugs. There is no indication in '715 that the temperature can be lower. Thus, even if for argument's sake one assumes that '991 and '715 can be combined, the result of such a combination will be melt blending UV cured polyurethane with oligomer in a solvent at between about 170 °C and 200 °C, which is vastly different from what we have claimed.

Nevertheless, to speed the prosecution of the present invention, Applicants have amended certain claims to "consisting essentially of polyurethane" so that there is no substantial amount of nonpolyurethane material in the melt-blendable polymer.

The Examiner further rejected claims 21,23-29, 31-32 under 35 USC 103 as being unpatentable over Re 32991 ('991, Szycher) in view of US 6010715 ('715, Wick), further in view of US6139866 ('866). The Examiner asserts that '866 teaches percutaneous formation to deliver fentanyl wherein the formulation is stable and has little irritation to the skin and excellent in percutaneous permeation of fentanyl and certain permeation enhancers (glycerol monolaurate) are mentioned. Applicants respectfully traverse the rejection.

First, '866 does not cure the deficiencies of '991 and '715. Second, '866 has NOTHING TO DO with having polyurethane in the **DRUG LAYER**, let alone melt-blendable at below about 150 °C. Polyurethane is only mentioned by '866 related to **BACKING** (see '866, column 5, lines

44-45). Nowhere does '866 mention that polyurethane is in the drug layer. Thus, regardless of whether '866 mentions fentanyl or enhancers, if polyurethane is NOT in the drug layer, what can a skilled person glean from using polyurethane in the drug layer? Nothing! A backing and a matrix have totally different functions and material requirement. If the matrix polymer is different, what can and should go into the matrix will definitely be different. By analogy, if a reference teaches one can incorporate lead into the peltier handle of a cooking pot, a reader skilled in the art will be insane to think he should incorporate lead into the steel body of the cooking pot based on that teaching on the handle. Similarly, one would never think of using a material from a backing in the matrix. Thus, claims 21,23-29, and 31-32 are novel and nonobvious over the cited references.

The Examiner also rejected claim 30 as being unpatentable over '991, in view of '715, and '866 and further in view of US5225199 ('199). Applicants respectfully traverse the rejection.

First, '866 does not cure the deficiencies of '991, '715, and '866. Second, '199 is entirely UNRELATED to making a melt-blended drug containing material. Rather, '199 is related only to making melt extruded **HOLLOW FIBER**, which is used in the **BACKING** (see '199, column 16, lines 30-50). Not only that, the melt extrusion of the *backing hollow fiber* is done at 285°C, a much higher temperature than what is claimed here! Regardless of what '866 says about enhancers, such enhancers have nothing to do with meltblendable polyurethane in '866. Again, similar to the lead in a pot analogy, a person will not put the cited enhancers in the matrix with the drug based on the '199 teaching. Thus, claim 30 is novel and nonobvious over the cited references.

Withdrawal of the rejections is respectfully requested.

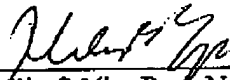
CONCLUSION

Applicants believe that no fee is due with this communication, although fees are due with the accompanying enclosures, all of which are itemized on the fee transmittal sheet. Conclusively, if it is determined that underpayment or overpayment has been made, the Director is authorized to debit or credit Deposit Account 10-0750, respectively.

Please direct any questions to the undersigned attorney at (650) 564-7054.

Respectfully submitted,

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